

Exhibit 9

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : MDL NO. 2327
PELVIC REPAIR SYSTEM, :
PRODUCTS LIABILITY : VOLUME VI
LITIGATION :

- - -

THIS DOCUMENT RELATES TO ALL CASES AND
VARIOUS OTHER CROSS-NOTICED ACTIONS
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- - -

February 4, 2014

- - -

Continued videotaped realtime
30(b)(6) deposition of JOHNSON & JOHNSON and
ETHICON, taken through it representative DANIEL J.
SMITH, was taken pursuant to notice and held at the
law offices of RIKER DANZIG SCHERER HYLAND PERRETTI
LLP, Headquarters Plaza, One Speedwell Avenue,
Morristown, New Jersey, beginning at 8:53 a.m. on
the above date, before Kimberly A. Cahill, a
Federally Approved Registered Merit Reporter and
Notary Public for the State of New Jersey.

- - -

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1 Q. In or about 2004-2005, Ethicon
2 started to explore more vigorously the concept of
3 cutting the TVT meshes using a laser; is that right?

4 A. In what timeframe?

5 Q. 2004-2005?

6 A. They may have. I believe they were
7 experimenting with ultrasonic cutting in that
8 timeframe.

9 Q. And part of the reason for that was
10 that there were complaints and perceptions in the
11 marketplace from the physicians that the
12 mechanically cut mesh was -- had some problems; is
13 that right?

14 MR. HUTCHINSON: Object to form.

15 THE WITNESS: I wouldn't necessarily
16 characterize it as a problem. Competitors would use
17 it -- it was -- against, from a selling perspective,
18 of the particle loss, but it was not ever deemed to
19 be clinically relevant.

20 BY MR. ZONIES:

21 Q. Well, there were complaints coming
22 from the field and it was known at Ethicon that
23 mechanically cut mesh frayed; is that right?

24 MR. HUTCHINSON: Object to form.

25 THE WITNESS: That is a term that was

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1 used, yeah.

2 BY MR. ZONIES:

3 Q. And that mechanically cut mesh had
4 particle loss or particles coming off of the mesh;
5 correct?

6 A. Or fraying.

7 Q. Also that mechanically cut mesh roped
8 or deformed and curled; correct?

9 MR. HUTCHINSON: Object to form.

10 THE WITNESS: It -- if stretched
11 beyond its elastic limit, yes.

12 BY MR. ZONIES:

13 Q. And laser cut mesh used -- strike
14 that.

15 Using a laser to cut the TVT mesh was
16 one of Ethicon's approaches to cut down on fraying
17 and particle loss; correct?

18 A. Yes, I would say that's...

19 Q. And also using the laser to cut the
20 mesh was one of Ethicon's ways to address the roping
21 and curling that could happen with mechanically cut
22 mesh; correct?

23 A. It was primarily done to my knowledge
24 for the particle loss.

25 Q. You say it was primarily for the

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1 particle loss. You do understand that was also to
2 address the roping, because the laser cut mesh would
3 not rope as much as mechanically cut; correct?

4 MR. HUTCHINSON: Object to form.

5 THE WITNESS: It's subjective to "as
6 much"; but if anything is stretched more than its
7 elastic limit, it will perform -- it'll rope.

8 BY MR. ZONIES:

9 Q. And the mechanically cut mesh would
10 reach that limit more quickly than laser cut;
11 correct?

12 A. Yes.

13 Q. It would rope more quickly than --
14 strike that.

15 Mechanically cut mesh would rope
16 under less force than laser cut; correct?

17 A. That would be correct; however, from
18 a -- you would have to, from an explanation
19 perspective, understand that those forces that you
20 are speaking about are far greater than the
21 physiological range and not normally seen in -- from
22 a clinical perspective.

23 MR. ZONIES: Move to strike after
24 "that would be correct."

25 BY MR. ZONIES:

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1 Q. Now, Mr. Smith, the laser cut mesh
2 would not rope as much as the mechanically cut mesh
3 because of the difference in its mechanical
4 properties due to the fashion in which it was cut;
5 correct?

6 A. Could you rephrase --

7 Q. Yeah, that was --

8 A. -- rephrase that; otherwise, I'm not
9 sure I can answer that --

10 Q. I'll rephrase.

11 A. -- or how to answer it, I should say.

12 Q. Sure. The laser cut mesh was stiffer
13 than the mechanically cut mesh and that's why it
14 wouldn't rope as quickly as mechanically cut
15 correct?

16 MR. HUTCHINSON: Object to form.

17 THE WITNESS: I would not be able to
18 agree with that as stated, no.

19 BY MR. ZONIES:

20 Q. Now, if a mesh ropes or when a mesh
21 is under stress, the pore size of the mesh can
22 change; correct?

23 A. Providing there's sufficient load.

24 Q. And the effective diameter of the
25 pores could change; correct?

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1 MR. HUTCHINSON: Object to form.

2 THE WITNESS: I couldn't agree with
3 that as stated. The word "diameter" makes no sense
4 in that context.

5 - - -

6 (Deposition Exhibit No. T-3587,
7 10-11/04 E-Mail Chain Among Lancos,
8 Castro, Smith, et al, ETH.MESH.01813975
9 through ETH.MESH.01813978, was marked for
10 identification.)

11 - - -

12 BY MR. ZONIES:

13 Q. Mr. Smith, I'm going to hand you
14 what's been marked as Exhibit 3587. It was
15 previously marked as 3160.

16 (Pause.)

17 BY MR. ZONIES:

18 Q. Have you reviewed -- Mr. Smith, you
19 have in front of you Exhibit 3587?

20 A. Yes, I do.

21 Q. Now --

22 MR. HUTCHINSON: I'm sorry. I'm
23 having -- I have 3160.

24 MR. ZONIES: It was previously marked
25 as 3160. I've re-marked it.

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1 MR. HUTCHINSON: All right.

2 MR. ZONIES: Do you want to keep the
3 old one instead?

4 MR. COMBS: No, no, that's fine.
5 Just tell me again --

6 THE WITNESS: 3587.

7 BY MR. ZONIES:

8 Q. Mr. Smith, you have in front of you
9 Exhibit 3587; it was previously marked as Exhibit
10 3160?

11 A. Yes, I do.

12 Q. And you can see that this is -- on
13 the top there, ends up being an e-mail that was
14 forwarded to you in 2004; is that right?

15 A. Yes.

16 Q. And the discussion in this e-mail is
17 about the top three complaints that Ethicon is
18 receiving about its TVT mesh; correct?

19 A. It appears to be, yes.

20 Q. And one of the top three complaints
21 is that the mesh is fraying; is that right?

22 A. Yes.

23 Q. So if you look down in the e-mail
24 from Laurent, you can see that the top three
25 complaints, mesh frayed, is on the top; is that

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1 right?

2 A. It's listed there, yes. I'm not sure
3 if it's the first or -- but it is listed there.

4 Q. And then it goes on to discuss that
5 and it says, "For Mesh frayed, so far there is no
6 official corrective action set up at Neuchatel" --
7 and Neuchatel's the manufacturing facility?

8 A. Of the finished product, not of the
9 mesh.

10 Q. -- and "This kind of complaint is
11 tracked," "knew by all people involved in TVT
12 business and especially technical people like Dan
13 SMITH." That's you. Right?

14 A. Yes, that's me.

15 Q. And that's true, isn't it, that this
16 was something that Ethicon knew about, that the mesh
17 that it used in the TVT frayed; correct?

18 A. If I could explain, it says tracked.
19 I do not track them. I did know about it, so just
20 clarifying --

21 Q. Sure.

22 A. -- the tracking piece versus the
23 knowing piece.

24 Q. And it's -- I don't know what's going
25 on today. Hang on -- Dave, I'm just going to pull

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1 this a little bit more. That's all. It keeps
2 catching.

3 Mr. Smith, that was true, correct,
4 that you and others, Ethicon, knew that one of the
5 characteristics of its TVT mesh was that the mesh
6 would fray; correct?

7 A. Yes.

8 Q. And this e-mail from Laurent goes on
9 to say, on the next page, that "the mesh frayed is
10 the reverse defect of the mesh features (elasticity
11 of the mesh is one of the commercial" arguments "to
12 market the TVT)."

13 And that's true, right, that the mesh
14 fraying was part of the elasticity; when the mesh
15 would get pulled under strain, it would fray;
16 correct?

17 MR. HUTCHINSON: Object to form.

18 THE WITNESS: I would not agree the
19 way that was stated, nor who wrote this. Does --
20 did the mesh lose particles? Yes. It -- I don't
21 think you could equate them back to the elasticity
22 as stated here.

23 BY MR. ZONIES:

24 Q. Okay.

25 So Laurent may have that part wrong.

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1 A. I'd have to -- you know, I'm not
2 quite sure what he's trying to get at. He's a
3 French-speaking individual. It might be English.
4 Don't know.

5 Q. And in any case, Laurent writes that
6 "the mesh frayed is the reverse defect of the mesh
7 features (elasticity of the mesh is one of the
8 commercial" arguments "to market the TVT)." That's
9 what he wrote; correct?

10 A. That's what's written.

11 Q. And --

12 A. From my understanding of that would
13 be when de Leval chose TVT, it was because of its
14 elastic properties. That may be what he's speaking
15 of there.

16 Q. Then he goes on to say, "However, the
17 root cause of the phenomenon are known; the way to
18 cut the mesh (blade cutting)" -- that means
19 mechanically cut, right, using a blade?

20 A. Yes.

21 Q. And that is indeed -- was known as
22 the cause of the fraying and particle loss; correct?

23 A. No. If I could explain, it was --
24 it's due to the construction of the mesh, not the
25 cutting of the mesh.

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1 Q. Mr. Smith, Laurent writes that "the
2 root cause of the phenomenon is known: the way to
3 cut the mesh (blade cutting). If we change the way
4 to cut the mesh (ultrasonic cutting or laser
5 cutting) it seems we can limit the mesh frayed
6 defect significantly."

7 Is that what he wrote there?

8 A. Yes.

9 Q. "Yes." And that was true, correct,
10 that if you changed -- if Ethicon changed the way of
11 cutting the mesh from blade cutting to laser
12 cutting, it could limit the fraying of the mesh;
13 correct?

14 MR. HUTCHINSON: Object to form.

15 THE WITNESS: Yes.

16 BY MR. ZONIES:

17 Q. Mr. Smith, I'm going to hand you
18 what's been previously marked as Exhibit 3161.

19 (Pause.)

20 BY MR. ZONIES:

21 Q. Mr. Smith, have you had a chance to
22 look at Exhibit 3161?

23 A. Yes.

24 Q. 3161's a Power Point entitled "LCM
25 Project" -- that's laser cut mesh project; correct?

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1 A. I would agree with that.

2 Q. Yeah -- and it says that it's
3 photographs comparing the laser cut mesh to
4 mechanically cut mesh. That's the title of it;
5 correct?

6 A. Yes. Sorry.

7 Q. If you turn to the first slide --
8 it's called "Side by Side," the first slide with a
9 picture on it -- do you see that?

10 A. Yes.

11 Q. Hang on just a second.

12 (Pause.)

13 MR. HUTCHINSON: Joe, we can go off
14 the record if you want to.

15 MR. ZONIES: Yeah, we can go off the
16 record.

17 THE VIDEO TECHNICIAN: We're going
18 off the record. The time is 9:15 a.m.

19 - - -

20 (A discussion off the record
21 occurred.)

22 - - -

23 THE VIDEO TECHNICIAN: Back on the
24 record. Time is 9:21 a.m.

25 BY MR. ZONIES:

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1 Q. Mr. Smith, you have Exhibit 3161 in
2 front of you?

3 A. I do.

4 Q. And that's a Power Point
5 presentation; and on the title page, it's the "LCM
6 Project" or laser cut mesh project; correct?

7 A. It appears so --

8 Q. And --

9 A. -- done by whoever ran the laser cut
10 program, yes.

11 Q. And it talks about the photographs
12 comparing laser cut mesh versus mechanically cut
13 mesh; is that right?

14 A. Yeah, that's what's shown here.

15 Q. If you turn to the first -- it's
16 actually the third slide of the Power Point
17 presentation, the first picture, it's called "Side
18 by Side."

19 Do you see that?

20 A. Yes.

21 Q. And on the left-hand side, it has
22 "MCM" standing for mechanically cut mesh; and on the
23 right-hand side, it says "LCM" for laser cut mesh;
24 is that right?

25 A. Yes.

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1 Q. And one of the things that the laser
2 cut mesh -- strike that.

3 One of the reasons that Ethicon
4 created the laser cut mesh and changed the way it
5 was cutting its mesh was to address what is seen on
6 the left-hand side where the arrow is pointing at
7 "Particles"; is that right?

8 A. Yes, but from an explanation
9 perspective, we were addressing particles. That is
10 a mesh that has been stretched, as it's stated, 50
11 percent, which is far beyond the clinical stretching
12 or what would be stretched in clinical use.

13 MR. ZONIES: Move to strike after "we
14 were addressing particles."

15 BY MR. ZONIES:

16 Q. So if we zoom in on the particles,
17 that is what is described in the earlier e-mails as
18 particle loss, which is a function of the fraying of
19 the mesh, is that right, the mechanically cut mesh?

20 A. Yes, providing that it would be
21 stretched in a normal manner. This was stretched
22 well beyond that, so you're seeing more particles.

23 MR. ZONIES: Move to strike after
24 "normal manner."

25 BY MR. ZONIES:

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1 Q. And the fraying is seen in this
2 photograph where on the edges of the mechanically
3 cut mesh, it's sort of lost its structure and it has
4 pieces of plastic sticking out and fraying; is that
5 right?

6 MR. HUTCHINSON: Object to form.

7 THE WITNESS: As I indicated, this
8 was stretched well beyond its elastic limit and not
9 clinically relevant stretching.

10 MR. ZONIES: Move to strike as
11 nonresponsive.

12 BY MR. ZONIES:

13 Q. Mr. Smith, my question is, is -- Mr.
14 Smith, the fraying that was described in the earlier
15 e-mail is, as we zoom in on this mechanically cut
16 mesh, it's what those edges of the mesh look like
17 where it's lost its structure and degraded; is that
18 right?

19 MR. HUTCHINSON: Object to form.

20 THE WITNESS: No, that is not
21 correct.

22 BY MR. ZONIES:

23 Q. And you can see on the slide above
24 where it says "Degradation" -- do you see that, Mr.
25 Smith?

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1 A. Yes.

2 Q. -- and it's pointing at, indeed, the
3 edges fraying of the mechanically cut mesh; is that
4 right?

5 MR. HUTCHINSON: Object to form.

6 THE WITNESS: That's what the
7 photograph shows, but not linked to the prior e-mail
8 that you just referred to.

9 MR. ZONIES: Move to strike after
10 "That's what the photograph shows."

11 BY MR. ZONIES:

12 Q. And if you turn to two slides later,
13 you see a slide entitled "Mesh Degradation"? Do you
14 have that in front of you, Mr. Smith?

15 A. Yes.

16 Q. And if you -- on the left-hand side
17 again is mechanically cut mesh, and on the
18 right-hand side is laser cut mesh; correct?

19 A. That's what they're labeled.

20 Q. And mechanically cut mesh has a label
21 saying "Loss of structure" and it has that frayed
22 look; is that right?

23 A. That's what the label says.

24 Q. And then on the right-hand side, it
25 says, for laser cut mesh, "Stretched, but" the

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1 "structure remains"; is that right?

2 A. At, I believe, the 50 percent
3 elongation, yes.

4 Q. And, Mr. Smith, that was, in fact,
5 one of the reasons that Ethicon created laser cut
6 mesh, was to ensure that the mesh didn't fray and
7 have particle loss when it was put under strain;
8 correct?

9 MR. HUTCHINSON: Object to form.

10 THE WITNESS: In the contents of this
11 e-mail, I would say, no. Particle loss, yes. But
12 this e-mail is not representative of why we were
13 doing that project.

14 BY MR. ZONIES:

15 Q. Mr. Smith, one of the -- if you turn
16 two slides later, there's a series of photos
17 entitled "Pre & Post Elongation." Do you see that?

18 A. Yes.

19 Q. And, again, on the left-hand side,
20 the first two photos are mechanically cut mesh and
21 the last two are laser cut mesh; is that right?

22 A. It appears to be that, right.

23 Q. And the post-elongation mechanically
24 cut mesh, what that's reflecting is what Ethicon
25 calls roping; is that right?

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1 A. I would not be able to agree with
2 that.

3 Q. Well, let's take a look. If you look
4 at the next page, it's a description of those
5 photographs. That's what it's entitled. Right?

6 A. Yes --

7 Q. And --

8 A. -- it's entitled that. Sorry.

9 Q. That's okay. And in the description,
10 it says, in the comparison between the
11 pre-elongation and post-elongation samples for the
12 mechanically cut mesh, it is seen that sometimes the
13 edges are slightly rough in the pre-elongation
14 samples -- so that means even before it's stretched,
15 the edges are rough from mechanically cut mesh.
16 Right?

17 A. By design.

18 Q. That's how it was designed; is that
19 right?

20 A. Yes, it was.

21 Q. And that's how Ethicon designed it,
22 to have rough edges for the mechanically cut mesh.
23 Right?

24 MR. HUTCHINSON: Object to form.

25 THE WITNESS: That's the construction

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1 of the mesh and what Professor Ulmsten actually
2 liked about the mesh, because it had its ability to
3 stick into tissue nicely when it was actually
4 implanted.

5 BY MR. ZONIES:

6 Q. This description goes on to say, in
7 the post-elongation sample of the mechanically cut
8 mesh, "the mesh has narrowed, roped prior to
9 relaxation and some of the knit has fallen apart."

10 That's what was written there; is
11 that right?

12 A. Whoever wrote it used that
13 terminology, yes.

14 Q. So if we turn back and look at what
15 was roped and lost its structure with fraying, that
16 would be the description of the second photo from
17 the left, the MCM post; is that right?

18 A. No, that would be an opinion of
19 whoever wrote this.

20 Q. And discussing that photograph of the
21 mechanically cut mesh; correct?

22 A. Stretched at 50 percent, yes.

23 Q. So laser cut mesh was designed in
24 part to deal with the roping and particle loss;
25 correct, Mr. Smith?

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1 A. I would say, no, it was really
2 designed -- because the mesh is identical, it was
3 really designed to address particle loss.

4 Q. Well, let's take a look at exhibit --
5 what's been previously marked as Exhibit 3162.

6 Exhibit 3162 is an e-mail in 2005
7 from Allison London Brown, is that right, discussing
8 laser cut mesh?

9 A. It appears to be, yeah --

10 Q. And --

11 A. I'm not in cc, so I'm not sure what's
12 in this e-mail.

13 Q. And she writes about laser cut mesh.
14 Do you see the paragraph that starts with "The basic
15 story"?

16 A. If you don't mind, let me just take a
17 quick second to read it since I've not seen this.

18 (Pause.)

19 THE WITNESS: I'm back.

20 (Pause.)

21 - - -

22 (A discussion off the record
23 occurred.)

24 - - -

25 BY MR. ZONIES:

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1 Q. Mr. Smith, have you had a chance to
2 review Exhibit 3162?

3 A. Yes, I have.

4 Q. Mr. Smith, Exhibit 3162 is an e-mail
5 from Allison London Brown in May of 2005 discussing,
6 the subject is, laser cut mesh; correct?

7 A. Yes.

8 Q. And you see the paragraph that begins
9 with "The basic story"?

10 A. Yes.

11 Q. She says that "The basic story here
12 is the current mesh (MCM)," mechanically cut mesh,
13 "is perceived by some physicians as inferior and we
14 do get a high number of complaints on linting and
15 roping (mesh particles falling off and the material
16 stretching to the point of being a string)."

17 That's what she wrote; correct?

18 A. That's what she wrote.

19 Q. And she says that "the new material,"
20 meaning laser cut -- right?

21 A. I believe so.

22 Q. -- "the new material will
23 dramatically reduce the incident of linting and
24 should all but eliminate the roping as it stays nice
25 and flat."

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1 Right? That's what she wrote?

2 A. That's what she wrote, yeah.

3 Q. And that's, indeed, Mr. Smith, what
4 you wrote in your e-mail if you look at what we
5 looked at yesterday -- it was 3162 -- you got that
6 in front of you?

7 A. Probably.

8 Q. I think it's the second one, actually
9 --

10 A. As in --

11 Q. From the top. Is that it there,
12 3162?

13 A. That's 3163.

14 Q. Oh, I'm sorry. Yeah. We were just
15 looking at --

16 A. Is that the one you want, 3163?

17 Q. 3163, right.

18 You have Exhibit 3163, Mr. Smith?

19 A. Yes.

20 Q. And what you wrote in Exhibit 3163 is
21 consistent with what Ms. London Brown wrote about
22 the laser cut mesh; correct?

23 A. Within the -- within reason, yes, in
24 terms of using those words, and from an R & D
25 perspective, what we would -- you know, if you

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1 THE WITNESS: So I would have to say
2 no, because it is a mischaracterization for that --
3 what this document is and the fact that -- that the
4 TVT has been known to have what we call a Velcro
5 effect, so even if it narrowed, it still holds in
6 tissue.

7 So you would have to go back to
8 actual studies to see if that would happen. This is
9 a -- it's a possibility and you would have to follow
10 that up with, does it really happen.

11 BY MR. ZONIES:

12 Q. What this describes is a possibility
13 or a potential, as that's entitled; correct?

14 A. Yes.

15 Q. And the potential that this describes
16 is -- a potential cause, in the right-hand column,
17 is, if there's roping, that potentially could cause
18 the mesh to slip; correct?

19 A. Theoretically. It's all theory.

20 Q. Potential; correct?

21 A. Potential that are rated and ranked
22 and weighed, yes.

23 Q. Right. So if the mesh roped, it has
24 the potential to cause the mesh to slip; and then
25 the harm that potentially results is, in that row at

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1 least, recurrence; correct?

2 A. If it was to happen.

3 Q. And that continues down, for example,
4 to the next row down, which says, "Reduction in mesh
5 width due to roping" is a potential cause of the
6 mesh slipping, in the first column; correct?

7 A. Yes.

8 Q. And if that occurs, that potentially
9 could cause erosion; correct?

10 A. If not placed correctly, yes.

11 Q. And, again -- if you go down to the
12 bottom one, it says --

13 A. The bottom one or the next one?

14 Q. I'm sorry. Two down from that, it
15 says, "Edge quality." Do you see that?

16 A. Not yet. Where are you? Oh, you're
17 in the other column over. Yes.

18 Q. Again, here in the potential cause of
19 the problem is the edge quality and that, if that
20 happens, could potentially cause the harm of pain;
21 correct?

22 A. I believe it's talking about the
23 sheath, though, isn't it? You're in a sheath
24 column. You've moved from -- from mesh to sheath.
25 So, again, that would not be a proper way to read

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1 this -- this chart.

2 Q. So, Mr. Smith, if you look down a few
3 rows, you see -- if you look down two rows, you can
4 see "Edge quality" as a potential cause of a
5 problem. It says "Edge quality (roughness, large
6 bead size)"; is that right, is that what that says?

7 A. It says that in the column under the
8 sheath.

9 Q. And if that potential cause occurs,
10 it can potentially cause mesh damage in the sheath
11 and, in turn, pain as the harm; correct?

12 MR. HUTCHINSON: Object to form.

13 THE WITNESS: I can't agree the way
14 you're looking at this chart. You're
15 misrepresenting this -- what this chart says.

16 BY MR. ZONIES:

17 Q. So let's go to the next page, Mr.
18 Smith, the same columns, rows 2, 3, and 4.

19 A. Rows 2, 3, and 4.

20 Q. And, again, reading the chart from
21 the right-hand side, it says "Potential Cause" and
22 the second row down says, "Reduction in mesh pore
23 size." Do you see that?

24 A. Yes.

25 Q. And if there's a reduction in mesh

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1 pore size, that could potentially cause a failure by
2 -- of the tissue ingrowth not occurring; correct?

3 A. Depending on the weighting and the
4 rating, yes.

5 Q. And the harm that could be caused to
6 the patient from that is that there could be a
7 foreign tissue reaction, a foreign body reaction;
8 correct?

9 MR. HUTCHINSON: Object to form.

10 THE WITNESS: No, with an explanation
11 that you have to -- in order to use this chart
12 correctly, you look at the severity. You look at
13 the rating and the occurrence.

14 And in those three categories, we're
15 looking at an RPN number of 7's and 8's, which is
16 extremely low. So, yes, it says that, but what it's
17 saying is that because we're using the Prolene mesh,
18 the chances of that happening are slim to none,
19 because the numbers are low.

20 So, yes, the words are there, but
21 this chart has to be used in conjunction with the
22 RPN number.

23 MR. ZONIES: Move to strike as
24 nonresponsive.

25 BY MR. ZONIES:

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1 Q. Mr. Smith, on the right-hand side for
2 rows 2, 3, and 4, they all say the same thing,
3 "Reduction in mesh pore size" as the potential
4 cause; correct?

5 A. Has the potential.

6 Q. And we've discussed before that pore
7 size reduction can happen when mesh is put under
8 strain; correct?

9 A. Correct.

10 Q. It might also happen, for example, if
11 mesh roped. When mesh ropes, like we saw in those
12 pictures, the pore size is collapsed completely;
13 correct?

14 A. Depending on how far it's stretched,
15 yes.

16 Q. And so if -- if that happens in this
17 -- according to this chart, if that happens, the
18 harm that can occur that's two columns over to the
19 left -- the harm that can occur potentially to a
20 patient if that happens includes tissue reaction,
21 recurrence of their stress urinary incontinence,
22 meaning it comes back, and erosion; is that right?

23 A. That's what it says, at a -- at a low
24 level, yes.

25 MR. ZONIES: Move to strike after

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1 "That's what it says."

2 BY MR. ZONIES:

3 Q. And the laser cut mesh, Mr. Smith,
4 was designed -- this is the design FMEA, right, it's
5 talking about the design of laser cut mesh?

6 A. Yes.

7 Q. The laser cut mesh was designed in
8 part to -- the laser cut mesh, Mr. Smith -- what
9 we're looking at is the design FMEA for laser cut
10 mesh; correct?

11 A. Yes.

12 Q. And it's demonstrating that part of
13 the reason to design the laser cut mesh was to
14 address these issues; correct?

15 A. No, I couldn't agree with that. It's
16 part of the -- the format for all the things that
17 would be looked at in the design of anything, we
18 look at all of the characteristics, so it is here,
19 but it's not the main -- it's not the reason why it
20 was being done. It's one of them. It's one of many
21 things we look at.

22 MR. ZONIES: So move to strike as
23 nonresponsive.

24 BY MR. ZONIES:

25 Q. What this shows, Mr. Smith, is that

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1 one of the reasons that laser cut mesh was being
2 developed was to address these issues; correct?

3 MR. HUTCHINSON: Object to form.

4 THE WITNESS: Yes, it's one of the
5 reasons.

6 BY MR. ZONIES:

7 Q. Now, eventually laser cut mesh was
8 actually put into Ethicon's devices; correct?

9 A. Yes.

10 Q. And --

11 A. Some of them. Sorry.

12 Q. The TVT Retropubic product is
13 available in laser cut; correct?

14 A. As well as mechanical.

15 Q. The TVT-O is available in laser cut;
16 correct?

17 A. As well as mechanical.

18 Q. And Ethicon chose, Mr. Smith, to
19 continue to sell mechanically cut mesh; correct?

20 A. That's correct; however, the reason
21 for that is because there is very good clinical
22 evidence that mechanical cut and laser cut have the
23 same clinical efficacy.

24 MR. ZONIES: Move to strike after
25 "That's correct."

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1 BY MR. ZONIES:

2 Q. So, Mr. Smith, I'm going to hand you
3 what's being marked as Exhibit 3588.

4 - - -

5 (Deposition Exhibit No. T-3588, Power
6 Point "Product Overview: Laser Cut Mesh,"
7 ETH.MESH.01730932, was marked for
8 identification.)

9 - - -

10 (Pause.)

11 MR. ZONIES: And the ETH.MESH. on
12 3588 is 01730932.

13 (Pause.)

14 BY MR. ZONIES:

15 Q. Mr. Smith, have you had a chance to
16 review 3588?

17 A. Yes.

18 Q. Mr. Smith, you have in front of you
19 Exhibit 3588 and it's entitled "Product Overview:
20 Laser Cut Mesh." Do you see that?

21 A. Yes.

22 Q. And this is a Power Point
23 presentation discussing some of the reasons to
24 create laser cut mesh; correct?

25 A. It's discussing the outcome of

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1 creating it, but, yes.

2 Q. Okay. Better put, this is a Power
3 Point presentation discussing the outcome of
4 creating laser cut mesh; correct?

5 A. Uh-hum. Yes. Sorry.

6 Q. So if you look, it says it's a new
7 processing technique; correct?

8 A. Yes.

9 Q. And it involves cutting the strips
10 with a laser instead of the current mechanical
11 method.

12 Then the fourth bullet point down
13 says, "the fraying of the edges and the loss of some
14 of the particles is reduced with the laser cut mesh
15 as compared to the mechanical cut mesh." The mesh
16 integrity is retained; correct?

17 A. That is one of the things it says,
18 yes.

19 Q. And that was, indeed, one of the
20 reasons to do laser cut mesh; correct?

21 A. That was one of them.

22 Q. If you turn to the next page of the
23 presentation, again, you see some photographs
24 comparing laser cut mesh before stretching and then,
25 on the right-hand side, laser cut and mechanically

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1 cut mesh after stretching; correct?

2 A. That's what's shown.

3 Q. And it says at the top with the
4 quotes "'Fray' & 'Stray' No More...Laser Cut Mesh";
5 is that right?

6 A. It sounds like a marketing cliché.

7 Q. That was the marketing term, right,
8 if you use laser cut mesh, you're not going to fray
9 and your mesh isn't going to stray; is that right?

10 A. You'd have to ask --

11 MR. HUTCHINSON: Object to form.

12 THE WITNESS: -- someone from
13 marketing.

14 MR. ZONIES: I'm sorry?

15 THE WITNESS: You'd have to ask
16 someone from marketing who created this document.

17 BY MR. ZONIES:

18 Q. And it discusses the benefits of
19 laser cut mesh, which includes, first, duller edges;
20 is that right?

21 A. Actually, that's what it says;
22 however, that was actually one of the, I think,
23 issues with laser cut mesh, that we weren't sure
24 that it was actually going to hold, because the
25 function of the mechanically cut mesh was actually,

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1 from a Velcro effect, to hold into tissue; and when
2 the laser cut mesh had duller edges, it may not have
3 stayed, so that testing had to be done.

4 MR. ZONIES: Move to strike after
5 "that's what it says."

6 BY MR. ZONIES:

7 Q. The other -- the -- one of the
8 benefits that's listed is decreased, quote, roping
9 effect; is that right?

10 A. That's what's listed here.

11 Q. And, indeed, that was one of the
12 reasons to create laser cut mesh; correct?

13 A. I couldn't -- my understanding, it
14 was primarily for the particle loss.

15 Q. Well, that was a big concern of
16 yours, the particle loss; correct?

17 MR. HUTCHINSON: Object to form.

18 THE WITNESS: Well, as I was
19 explaining, they both rope regardless -- I mean,
20 this document here does not say what the loads were
21 that these were put under, so it's -- it's a picture
22 trying to show an effect.

23 BY MR. ZONIES:

24 Q. They both rope.

25 A. They both have -- they both rope.

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1 Q. So, Mr. Smith, if we zoom in on the
2 "After Stretching" picture, on the left-hand side is
3 the laser cut, on the right-hand side is the
4 mechanically cut; is that right?

5 A. It's -- I believe, yes.

6 Q. I'm sorry. On the right hand
7 picture, the "After Stretching"?

8 Mr. Smith, if you look at the "After
9 Stretching," you can see a difference between these
10 two meshes, the laser cut on the left-hand side
11 after stretching versus the mechanically cut mesh on
12 the right-hand side, where the mechanically cut mesh
13 has lost its structure and certainly the pores have
14 collapsed; is that right?

15 MR. HUTCHINSON: Object to form.

16 THE WITNESS: I would not agree with
17 that as stated. They both have narrowed, I think,
18 fairly equally. The mechanically cut has lost the
19 edge quality, which actually may not affect it from
20 a holding perspective, but in the picture, it is --
21 the edges are different.

22 BY MR. ZONIES:

23 Q. As you said, the mechanically cut has
24 lost its edge quality; correct?

25 A. From where it started, yes.

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1 Q. And both of them, when put under
2 strain, the pour sizes seem to have collapsed
3 somewhat; correct?

4 MR. HUTCHINSON: Object to form.

5 THE WITNESS: In this picture, yes.

6 MR. ZONIES: Mr. Smith, I'm going to
7 hand you what's being marked as Exhibit 3589.

8 - - -

9 (Deposition Exhibit No. T-3589, Memo
10 from Allison London Brown to Dan Smith Re:
11 Mechanical Cut vs. Laser Cut Mesh
12 Rationale, ETH.MESH.00858252 and
13 ETH.MESH.00858253, was marked for
14 identification.)

15 - - -

16 MR. ZONIES: Just take a minute and
17 review that. ETH.MESH. number is 00858252.

18 (Pause.)

19 BY MR. ZONIES:

20 Q. Mr. Smith, you have in front of you
21 Exhibit 3589?

22 A. Yes.

23 Q. And it's a memorandum from Allison
24 London Brown to you, Dan Smith, regarding mechanical
25 cut versus laser cut mesh rationale; is that right?

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1 A. Yes, among some other things, yes.

2 Q. And she writes -- Ms. London Brown
3 writes to you, Dan Smith, that "In the fall of 2004,
4 work was re-initiated to approve a change in the
5 processing of PROLENE mesh used in the GYNECARE TVT
6 systems"; is that right?

7 A. I believe she was referring to the
8 ultrasonic cutting that might have come before that
9 and the reinitiation of it, yes.

10 Q. In other words, there was -- much
11 earlier, before 2004, Ethicon was looking at whether
12 or not it should cut its meshes differently than
13 with mechanically cut mesh; correct?

14 A. I believe they were.

15 Q. And she writes that the rationale for
16 the TVT base business was a customer need to fix a
17 problem; is that right?

18 A. That's what she has written here.
19 Again, particle loss.

20 Q. Right. She says two things, two
21 reasons, under "Customer Need: FIX A PROBLEM" --
22 number 1, "Customer Need: FIX A PROBLEM. The
23 Market place (Europe specifically) was experiencing
24 some challenges from surgeons who were using stiffer
25 meshes with different construction, which had less

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1 particle loss" -- that's what you were pointing out,
2 the particle loss. Right?

3 A. It's in numerous places in here.

4 Q. -- less particle loss than
5 mechanically cut mesh and less mesh distortion
6 during implantation than mechanically cut mesh;
7 correct?

8 A. That's what it says. I believe she's
9 referring to many other comparative meshes that are
10 on the market that are stiffer.

11 Q. And she says the -- in the next
12 paragraph, "The particulate loss in question was
13 attributed to the stretching of the mesh" --
14 mechanically cut mesh -- "during implantation and,
15 at times, difficult removal of the sheaths, causing
16 loops created during the knitting process, but cut
17 during processing to fall off"; correct?

18 A. That's what's stated.

19 Q. In other words, pieces of mesh from
20 the mechanically cut mesh were falling off during
21 implantation and also when there was difficult
22 removal of sheaths; correct?

23 A. It's the particle loss.

24 Q. Of mechanically cut mesh. Right?

25 A. Yes.

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1 Q. And then she goes on to say,
2 "Additionally, the mechanically cut (MC)" -- the
3 mechanically cut mesh "can be stretched to
4 deformation, creating a rope," in quotes, "if not
5 placed properly." That's what she wrote. Right?

6 A. That's what she wrote.

7 Q. Some physicians, she continues,
8 perceived this could irritate or damage the urethra.
9 Right?

10 A. It was a perception of those.

11 Q. And, again, those were the -- two of
12 the reasons that Ethicon was creating -- strike
13 that.

14 And, again, those are two of the
15 reasons why Ethicon was changing the cutting method
16 to laser cut from mechanically cut; correct?

17 A. It was one of the reasons why we were
18 doing that, change the manufacturing process,
19 perhaps, you know, improve on the particle loss.
20 There was no evidence that it would -- as stated
21 here, would irritate or damage the urethra. It was
22 perceived.

23 Q. It was perceived and if you recall,
24 the laser cut, we looked at the design FMEA and it
25 was talking about part of the reason to create laser

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1 cut mesh was to address the potential for pore size
2 change, for fraying that might cause erosion or
3 pain; is that right?

4 MR. HUTCHINSON: Object to form.

5 THE WITNESS: No, I believe I
6 disagreed with the way that was being looked at from
7 that chart.

8 BY MR. ZONIES:

9 Q. And that chart, however, described
10 erosion and pain as some of the reasons that Ethicon
11 was developing the laser cut mesh instead of the
12 mechanically cut mesh; correct?

13 MR. HUTCHINSON: Object to form;
14 mischaracterizes his testimony.

15 THE WITNESS: No, again, it was, as
16 we develop things, we always list all of the
17 possible -- possibilities and then rank and rate
18 them. And they're on the chart because we look at
19 everything -- everything.

20 BY MR. ZONIES:

21 Q. Right, and Mr. Smith, if you look at
22 Exhibit 3585 -- it was from yesterday. You may have
23 that in front of you -- Mr. Smith, if you look at
24 Exhibit 3585, this is a memorandum from 1999; is
25 that right?

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1 A. I believe if we're looking at the
2 same one it's regarding hernia meshes, right, from
3 Bob Rousseau? Yes.

4 Q. Yes, Exhibit 3585 is a memorandum --
5 the initial memorandum's August 18th, 1999; is that
6 right?

7 A. Yes. I was looking at the top is
8 September.

9 Q. And this is discussing, "As we had
10 discussed, there are three generations of mesh."
11 Right?

12 A. Hernia meshes, yes.

13 Q. And the first generation, called old,
14 old mesh is utilized currently in the TVT product;
15 is that right?

16 A. Yes.

17 Q. And this is in 1999; correct?

18 A. It's when the memo was created, yes.

19 Q. And then it talks about a second
20 generation old mesh, which is currently utilized in
21 Scotland for normal Prolene, flat mesh. Right?

22 A. For hernias.

23 Q. Then it talks about a third
24 generation (new or 5-mil) mesh, which is currently
25 in production in San Lorenzo. Right?

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1 A. For hernia mesh, yes.

2 Q. And there, if you look at that, Mr.
3 Smith, it's discussing how way back in 1999, when
4 the TVT was first on the market, they were laser
5 cutting the mesh; is that right?

6 MR. HUTCHINSON: Object to form.

7 BY MR. ZONIES:

8 Q. Do you see where it says laser
9 cutting in that paragraph?

10 A. No. Which paragraph are you looking
11 at, third paragraph?

12 Q. Third paragraph, the third generation
13 or new mesh, way back in 1999, and they're
14 performing some laser cutting. Do you see that?

15 A. That's what it says, I guess. I
16 haven't found it on here, but -- oh, yes, here we
17 go.

18 Q. And as a matter of fact, if you look
19 up in the first paragraph, that's what this memo is
20 about. It says, "I am forwarding this message to
21 you regarding your request for mesh samples to
22 perform laser cutting experimentation in Scotland."
23 Right?

24 A. That's what Bob Rousseau wrote, yes.

25 Q. In 1999. And yet, from 1999 until

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1 2006, Ethicon never used laser cutting to cut its
2 TVT mesh; correct?

3 A. There was no reason to. I mean, this
4 is -- we're still -- we're still not using -- we're
5 still using mechanical cut because there is clinical
6 evidence that says mechanical -- there's nothing
7 wrong with mechanical cut.

8 Q. Mr. Smith, that's -- to this day --
9 can we pull up the picture, please, of the laser cut
10 mesh next to mechanically cut mesh? Exhibit 3161?

11 As a matter of fact, Mr. Smith, if
12 you have in front of you Exhibit 3161, to this day,
13 Ethicon continues to sell this mesh on the left-hand
14 side of this picture; correct?

15 A. Absolutely incorrect. That mesh in
16 that picture is a mischaracterization for
17 demonstration purposes at 50 percent elongation. 50
18 percent elongation is ten times more than what you
19 would use clinically.

20 MR. ZONIES: Move to --

21 THE WITNESS: The physiological range
22 is between 5 and maybe 10 percent elongation. This
23 was done by someone -- probably Gene Kammerer given
24 the date and the time for laser cut -- for
25 demonstration purposes.

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1 MR. ZONIES: Move to strike as
2 nonresponsive.

3 BY MR. ZONIES:

4 Q. Mr. Smith, it's true, isn't it, that
5 to this day and since 1999 -- move -- strike that.

6 Mr. Smith, it's true, isn't it, that
7 in 1999, Ethicon had the capabilities to create the
8 laser cut mesh that's seen on the right side of this
9 photograph; correct?

10 MR. HUTCHINSON: Object to form.

11 THE WITNESS: It may be true;
12 however, from an explanation perspective, just
13 because technology exists, the clinical evidence of
14 TVT being mechanically cut from Professor Ulmsten
15 initially was the clinical evidence for TVT and it
16 was mechanically cut and it still is today.

17 MR. ZONIES: Move to strike after "It
18 may be true."

19 BY MR. ZONIES:

20 Q. And yet, from 1999 until today,
21 Ethicon still sells mechanically cut mesh; is that
22 correct?

23 A. Mechanically cut mesh is sold today,
24 yes.

25 Q. Despite the fact that Ethicon knows

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1 it has particle loss and fraying; correct?

2 MR. HUTCHINSON: Object to form.

3 THE WITNESS: Particle loss and
4 fraying is not clinically relevant.

5 BY MR. ZONIES:

6 Q. Mr. Smith, Ethicon knows, as shown in
7 this picture, that mechanically cut mesh has
8 particle loss; is that right?

9 A. Mechanically cut mesh has particle
10 loss which has been deemed by our medical officials
11 to be nonclinically relevant, yes.

12 Q. Particle loss was very important to
13 you personally, wasn't it, Mr. Smith?

14 A. I -- as an R & D engineer, I dealt
15 with it, yes.

16 Q. I mean, let's take a look at Exhibit
17 366. You wrote this memo, this e-mail, in February
18 of 2004, didn't you?

19 A. I believe I did, yes. I believe
20 we've looked at it already.

21 Q. About what you've described as
22 brittle mesh. Right?

23 A. I would have to read it to -- if I
24 did, I did.

25 Q. If you look at the one, two, three,

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1 fourth paragraph down, "This is not going away
2 anytime soon and competition will have a field day,
3 major damage control offensive needs to start to
4 educate the reps and surgeons UPFRONT that they will
5 see BLUE shit and it is OK."

6 That's what you wrote about the
7 particle loss. Right?

8 A. Yes, because we were changing the
9 process -- process going to blue and we always have
10 had particle loss. As a clear mesh, particle loss
11 has been part of the TVT from its inception; and
12 without going to laser cut mesh, you would see more
13 particle loss.

14 Obviously, I could have used a better
15 choice of words, but it is okay, is what it says,
16 because our medical directors have said particle
17 loss was not clinically relevant.

18 Q. The roping that laser cut mesh was
19 intended to address was, however, clinically
20 relevant and the laser cut mesh actually did address
21 the roping; correct?

22 A. If someone was to stretch it beyond
23 its elastic limit on purpose, yes.

24 Q. And if there was, indeed, less
25 roping, then there would be, as the chart showed,

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1 less erosion, less pain, less recurrence, and less
2 retention; correct?

3 A. No, I can't agree to that. Again,
4 that chart is being mischaracterized.

5 Q. That's what was on the chart, though,
6 correct, that if there's roping, there's a potential
7 to cause erosion; correct?

8 A. No, there's -- it's on the chart
9 because if a surgeon did not put it properly and you
10 had roping, that could happen clinically. So,
11 again, the chart needs to be looked at holistically.

12 Q. If there was roping, it could cause
13 erosion; correct?

14 A. If the surgeon didn't put it in
15 correctly.

16 Q. If -- move to strike as
17 nonresponsive.

18 Mr. Smith, if there was roping --
19 that's what the chart says -- if there was roping,
20 for whatever reason, it could cause erosion;
21 correct?

22 A. No, that's --

23 MR. HUTCHINSON: Object to form.

24 THE WITNESS: -- not what the chart
25 says.

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1 BY MR. ZONIES:

2 Q. To this day, Mr. Smith, it's true,
3 isn't it, that Ethicon still sells the mechanically
4 cut mesh that you're discussing in this e-mail, and
5 that Ethicon still sells this mesh where physicians
6 may see blue shit all over the place. Right?

7 MR. HUTCHINSON: Object to form;
8 argumentative.

9 THE WITNESS: I think I've answered
10 we sell both blue and clear mesh in mechanically cut
11 form.

12 MR. ZONIES: Why don't we take a
13 break.

14 THE VIDEO TECHNICIAN: We're going
15 off the record. The time is 10:27 a.m.

16 (A recess was taken from 10:27 a.m.
17 to 10:57 a.m.)

18 THE VIDEO TECHNICIAN: We're back on
19 the record. This is the beginning of disc number 2.
20 The time is 10:57 a.m.

21 BY MR. ZONIES:

22 Q. Mr. Smith, we're back from break.
23 Are you ready to go?

24 A. Yes.

25 MR. ZONIES: Mr. Smith, I'm handing

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1 Q. Okay.

2 And then what did you say about the
3 elongation?

4 A. So the elongation as indicated in the
5 back of here at 800 grams would be at the top of the
6 chart or at the far right-hand side of this chart,
7 so well beyond the physiological range.

8 Q. Mr. Smith, let's look at Exhibit
9 3589, if we can, please. Do you remember being
10 asked questions about this document?

11 A. Yes, I do.

12 Q. And is this a memo to you from
13 Allison London Brown about mechanically cut versus
14 laser cut mesh?

15 A. Yes.

16 Q. And Mr. Smith, if we look at the
17 second paragraph under "Customer Need," it begins
18 with "The particulate loss in question" -- do you
19 see that?

20 A. Yes.

21 Q. -- and do you recall the plaintiffs'
22 lawyer asking you questions about that paragraph?

23 MR. ZONIES: Object to the form.

24 THE WITNESS: I don't -- I was asked
25 from many things, so not -- I mean...

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1 BY MR. HUTCHINSON:

2 Q. Let's look at the last sentence of
3 that paragraph that begins with "Particle lost."
4 What does it state?

5 A. "Particle lost is not clinically
6 significant and has always been present with the
7 Gynecare TVT mesh," which would be the mechanical
8 cut mesh.

9 Q. What does that mean?

10 A. It means that it's not an issue.
11 It's been determined by medical and clinical that it
12 is not significant, it's not -- does not have a
13 clinical impact.

14 MR. ZONIES: Move to strike as beyond
15 the scope.

16 BY MR. HUTCHINSON:

17 Q. And Mr. Smith, the particle loss
18 that's referenced in this exhibit, would that be the
19 same particle loss that we looked at in the
20 photograph that compared mechanically cut versus
21 laser cut mesh where they both were relaxed after 50
22 percent elongation?

23 MR. ZONIES: Object to the form.

24 THE WITNESS: Yes.

25 BY MR. HUTCHINSON:

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1 Q. Let's turn to Exhibit 366, please.

2 A. I'm sorry. The number? What number?

3 MR. ZONIES: 366.

4 MR. HUTCHINSON: 366.

5 THE WITNESS: 366?

6 MR. HUTCHINSON: Correct.

7 THE WITNESS: Three numbers.

8 MR. HUTCHINSON: Yeah, it's -- can we
9 go off the record for a minute while he finds it?

10 THE VIDEO TECHNICIAN: We're going
11 off the record. The time is 2:57 p.m.

12 - - -

13 (A discussion off the record
14 occurred.)

15 - - -

16 THE VIDEO TECHNICIAN: We're back on
17 the record. Time is 2:59 p.m.

18 BY MR. HUTCHINSON:

19 Q. Mr. Smith, do you recall being asked
20 questions about this e-mail?

21 A. Yes, I do.

22 Q. And is this an e-mail from you to
23 Janice Burns, dated February 27, 2004?

24 A. Yes, it is.

25 MR. HUTCHINSON: And, Mr. Lawlor, if

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1 you will, would you highlight the paragraph that
2 begins with "This is not going away"?

3 BY MR. HUTCHINSON:

4 Q. Do you see that, Mr. Smith?

5 A. Yes, I do.

6 Q. Is that something you wrote?

7 A. Yes, it is.

8 Q. What was going on at the company at
9 the time you wrote this e-mail?

10 A. My understanding of this e-mail and
11 what was going on at the company at the time was, we
12 were -- competition was taking our mesh and
13 stretching it in front of prospective customers over
14 different-colored paper and rubbing the edges and
15 showing them that, look at all these particles that
16 are falling off, and using it to basically try to
17 say that the mesh was inferior when, in fact, it had
18 the largest clinical data.

19 So what I was saying here was that,
20 obviously, they were going to have a field day and
21 we needed to have a statement from management that
22 -- so that everyone had the same information and was
23 -- would be able to counter the measures that the
24 competition was doing by destroying the mesh.

25 And then -- that was the intent of

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1 this.

2 Q. Mr. Smith, let's turn, if we will, to
3 Exhibit 3585.

4 A. Filament; correct -- no, sorry.

5 Q. Do you have that document in front of
6 you?

7 A. I do.

8 Q. And I want to turn your attention to
9 the e-mail from Bob Rousseau or Robert Rousseau,
10 rather, dated August 18, 1999. Do you see that?

11 A. Yes.

12 Q. And what does the first sentence
13 state?

14 A. "I am forwarding this message to
15 yourself regarding your request for mesh samples to
16 perform laser cutting experiments in Scotland."

17 Q. Mr. Smith, you were asked a lot of
18 questions about laser cutting mesh. Do you remember
19 that?

20 A. Yes.

21 Q. Was laser cut technology available at
22 Ethicon in 1999 or was it in the experimental stage?

23 MR. ZONIES: Object to the form.

24 THE WITNESS: Well, based on this
25 e-mail, which was not to me, it was the beginning

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1 stages called experimentation.

2 MR. HUTCHINSON: Mr. Smith, thank you
3 for your time. I don't have any further questions.

4 THE WITNESS: Thank you.

5 THE VIDEO TECHNICIAN: We're going
6 off the record. The time is 3:02 p.m.

7 (A recess was taken from 3:02 p.m.
8 to 3:10 p.m.)

9 THE VIDEO TECHNICIAN: We're back on
10 the record. Here begins disc number four of the
11 deposition of Dan Smith. The time is 3:10 p.m.

12 - - -

13 EXAMINATION

14 - - -

15 BY MR. ZONIES:

16 Q. Mr. Smith, if you could -- just a few
17 follow-up questions -- if you could pull out Exhibit
18 3582 -- Mr. Smith, Joe Zonies again for plaintiffs.

19 If you could pull out Exhibit 3582.
20 Do you have that in front of you?

21 A. Yes.

22 Q. This is a marketing piece and it says
23 there on the front of it "Gynecare TVT Family of
24 Products" in the bottom-right corner; is that right?

25 A. It does.

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1 Q. Do you have in front of you Exhibit
2 3587?

3 Leave that picture up, please. I
4 just want to talk about those particles.

5 A. I'm sorry. Can you repeat that
6 number?

7 Q. Sure. Do you have in front of you,
8 please, Mr. Smith, Exhibit 3587, which was
9 previously marked as 3160?

10 A. I do.

11 Q. Exhibit 3587 is an e-mail in 2004
12 that was forwarded to you discussing that one of the
13 top complaints about TVT meshes was that the mesh
14 would fray; is that right?

15 A. It's about fraying, yes.

16 Q. And what we're seeing in the picture
17 that's up on the screen, those particles, that is,
18 particle loss is mesh fraying; is that correct?

19 A. Yes.

20 MR. HUTCHINSON: Object to form.

21 MR. ZONIES: I'm sorry?

22 THE WITNESS: Yes.

23 By MR. ZONIES:

24 Q. And as described in this e-mail by
25 Laurent Treyvaud, the mesh fraying -- he's

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1 discussing how laser cutting the mesh, which is what
2 we see on the right up here, would, quote, limit the
3 mesh frayed defect, close quote; is that right? Is
4 that what he wrote?

5 MR. HUTCHINSON: Object to form.

6 THE WITNESS: I'm not sure where you
7 are, but if it says that -- but if I could -- I
8 mean, it also in here talks that it's due to the
9 construction. I think we've established that mesh
10 fraying is due to the construction and it has no
11 clinical issues.

12 MR. ZONIES: Move to strike after "if
13 it says that."

14 BY MR. ZONIES:

15 Q. So, Mr. Smith, if my client had a
16 mechanically cut mesh implanted, that mechanically
17 cut mesh had the potential to rope, had the
18 potential to have particle loss, had the potential
19 to have the fraying defect described in this e-mail;
20 correct?

21 MR. HUTCHINSON: Object to form.

22 THE WITNESS: I could not agree with
23 that. I would say that the top surgeons still use
24 mechanically cut mesh; and if your client had such
25 defects, it would most likely be that -- the surgeon

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1 error.

2 BY MR. ZONIES:

3 Q. You'd blame the doctor, wouldn't you,
4 Mr. Smith?

5 A. No. I'm -- you're asking my opinion.

6 Q. If you turn to Exhibit 3591, Mr.
7 Smith, this is an e-mail that discusses the
8 mechanically cut mesh having sharp edges.

9 Do you recall looking at this?

10 A. Same document or is this a different
11 one?

12 Q. It's Exhibit 3591. And it's the one
13 that actually has the pictures of the mechanically
14 cut mesh and its sharp edges.

15 MR. HUTCHINSON: I'm going to object
16 to the form of the question.

17 BY MR. ZONIES:

18 Q. Do you have Exhibit 3591 in front of
19 you, Mr. Smith?

20 A. I do.

21 Q. And this is an e-mail that says on
22 the first paragraph that the mechanically cut mesh
23 can provide sharp edges; is that right?

24 MR. HUTCHINSON: I'm going to object
25 to the extent that mischaracterizes the document.

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1 THE WITNESS: In my opinion, "sharp"
2 is very subjective; and in this particular case, it
3 comes -- it comes to an edge that isn't round, but
4 that does not mean it's going to cut you in terms of
5 sharp, so -- "sharp" is very relative.

6 BY MR. ZONIES:

7 Q. Well, let's take a look at the
8 picture. Go ahead. Show the picture of the
9 mechanically cut mesh that my client had. It's the
10 one -- the bottom two.

11 The jury can decide if those are
12 sharp edges, but you would agree, wouldn't you, Mr.
13 Smith, that that is mechanically cut mesh?

14 A. This is mechanically cut mesh.

15 Q. With those sharp edges; correct?

16 MR. HUTCHINSON: Object to form.

17 THE WITNESS: No, I can't agree with
18 that. There has -- it's been cut. It has not been
19 laser cut. It's been mechanically cut. I can't
20 agree to sharp. Sharp -- surgical scalpels are
21 sharp. That would not cut you.

22 BY MR. ZONIES:

23 Q. That piece of plastic cut like that,
24 you don't think that would cut a human being.

25 A. I know it wouldn't.

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1 MR. HUTCHINSON: Object to form.

2 THE WITNESS: I mean, it's a piece of
3 plastic. It's soft plastic.

4 (Pause.)

5 MR. ZONIES: Can we go off the
6 record?

7 THE VIDEO TECHNICIAN: Going off the
8 record. The time is 3:31 p.m.

9 - - -

10 (A discussion off the record
11 occurred.)

12 - - -

13 THE VIDEO TECHNICIAN: We are back on
14 the record. Time is 3:47 p.m.

15 BY MR. ZONIES:

16 Q. Mr. Smith, we're back on the record
17 and before we broke, we were looking at a picture of
18 -- a zoomed-in picture of the mechanically cut mesh
19 and what was described in the e-mail attaching the
20 picture as its sharp edges.

21 Do you recall that?

22 MR. HUTCHINSON: I'm going to object
23 to form.

24 THE WITNESS: I recall the picture.

25 BY MR. ZONIES: